May 10, 2019

Hon. Paul W. Grimm
United States District Judge
6500 Cherrywood Lane
Greenbelt, MD 20770

RE: American Academy of Pediatrics, et al., v. FDA (No. 8:18-cv-883-PWG)

Dear Judge Grimm,

FDA's Response is noticeably silent about how long it will take to issue final guidance. It cannot say if, much less when, it will replace the 2017 Guidance, and does not dispute that action this year is unlikely. Far from providing reason to expect imminent action, FDA's filing and its comments in the April 18, 2019 teleconference omit major hurdles the agency must clear before issuing a new final guidance. Instead of providing an accurate picture or meaningful assurances, FDA advances a view of ripeness that omits the actual legal test and sweeps so broadly that agencies could always delay or evade judicial review by merely considering policy changes. FDA's Response thus confirms that the Court should reinstate the parties' cross-motions.

In response to the Court's questions in the teleconference about the steps remaining before issuance, FDA omitted substantial, time-consuming steps it needs to clear before issuing the proposed guidance, which are similarly missing from its Response. The Office of Information and Regulatory Affairs ("OIRA") of the Office of Management and Budget ("OMB") has mandated all agencies to submit all "guidance documents" to OIRA for review prior to publication, with limited exceptions not applicable here.[1] First, the agency undertakes a cost-benefit analysis structured by a 48-page OMB Circular to determine the action's economic impact. OIRA Memo at 6.[2] OIRA then conducts its own analysis to determine whether the action is "major," which may require additional information from the agency. *Id.* This process typically took several months even before OIRA expanded the range of actions it reviewed, and is presumably even slower today due to OIRA's increased workload.[3] If OIRA deems the action

[1] *See* Memorandum from Russell T. Vought, Acting Dir., OMB, to the Heads of Exec. Dep'ts & Agencies at 3 (Apr. 11, 2019) ("OIRA Memo"), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf. The OIRA Memo is in "full effect" as of May 11, 2019. *Id.* at 2. Plaintiffs do not intend to suggest agreement with the OIRA Memo, but only to state the requirements the current administration has set for all agencies.
[2] *See* OMB, Circular A-4 (2003), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.
[3] *See* Maeve P. Carey, Congressional Research Service, Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the *Federal Register* at 13 (Oct. 4, 2016), https://fas.org/sgp/crs/misc/R43056.pdf (over last four years analyzed, the average review took 107 days).

major, it cannot take effect until 60 days after submission to Congress. *Id.* at 3-4. Thus even issuance "as quickly as possible" may require many months of delay, on top of the time FDA needs to review and respond to the hundreds of "more detailed" comments it has received, Def.'s Resp. at 5, ECF No. 71, and undertake the analysis required by OIRA.

Instead of grappling with the actual consequences of leaving the challenged guidance in place indefinitely, FDA relies almost exclusively on "prudential ripeness," an "exception to the usual rule that where jurisdiction exists a federal court must exercise it." *Simmonds v. INS*, 326 F.3d 351, 357 (2d Cir. 2003). The Supreme Court has unanimously questioned this doctrine's "continuing vitality," *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014),[4] but even assuming its viability, FDA has not met its requirements.

Those requirements, which FDA never once acknowledges, are two-fold. A court must "evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Ass'n v. U.S. Dep't of Interior*, 538 U.S. 803, 808 (2003). The fitness of an issue "depends on whether it is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 387 (D.C. Cir. 2012) (citation omitted). FDA does not address *any* of these considerations.

Under this test, Plaintiffs' claims are plainly ripe. The issues are fit for judicial decision: they are purely legal; do not require further factual development; and, as explained previously, concern final agency action. *See* Pls.' Summ. J. Reply at 14-17, ECF No. 39. Rendering the operative Guidance unchallengeable would cause hardship to Plaintiffs, to say nothing of the millions of young people who are becoming addicted to products that continue to be marketed solely because the illegal 2017 Guidance remains in effect. *See id.* at 2-14.

None of the cases FDA cites support its expansive view of prudential ripeness, nor do any apply it in a remotely comparable context.[5] The action challenged in this case permits the illegal marketing of products that are addicting thousands of new users every day. FDA has not

[4] *See id.* (doctrine is "in some tension with our recent reaffirmation of the principle that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging" (internal quotation marks omitted)).

[5] *See Nat'l Park Hospitality*, 538 U.S. at 809-10 (dispute over agency's interpretation of statutory term unripe where agency was "not empowered to administer the [underlying statute]" and "[a]ll the regulation does is announce the position [the agency] will take with respect to disputes arising out of concession contracts"); *Am. Petroleum*, 683 F.3d at 389-90 (dispute over agency decision not to extend exclusion to plaintiffs' products unripe where agency was bound by settlement to take new final action in six months and plaintiff had not shown ability to benefit from earlier extension); *AT&T Corp. v. FCC*, 369 F.3d 554, 556-57, 562-63 (D.C. Cir. 2004) (where prior safeguards had "sunset 'by operation of law,' not by [agency] action," challenge to failure to issue new safeguards was unripe); *Utility Air Regulatory Grp. v. EPA*, 320 F.3d 272, 279 (D.C. Cir. 2003) (dispute over agency interpretation of permit statute unripe where interpretation was under review and agency had not "take[n] action affecting a permit pursuant to the challenged interpretation"); *Pub. Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 32-33 (D.C. Cir. 1984) (rejecting claim that agency was bound by unfinalized proposed rule); *Lake Pilots Ass'n, Inc. v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 161-62 (D.D.C. 2003) (portion of complaint challenging rate-setting unripe where agency had already issued temporary final rule restoring previous rates).

identified a single case where prudential ripeness prevented a party from challenging an operative agency action that authorized ongoing conduct that would otherwise be unlawful—let alone where the sole basis for unripeness was that the agency had proposed eventually taking a different action. If that alone rendered cases unripe even where the challenged action remained in effect and had ongoing, tangible consequences, agencies could escape any challenge simply by proposing a change. Applied as Defendants urge, prudential ripeness has no limiting principle.

Moreover, Defendants' reading is incompatible with well-established law. Under the voluntary cessation doctrine, post-litigation changes in agency conduct do not moot a plaintiff's claims unless defendants carry the "heavy burden" of showing "that there is no reasonable expectation that the alleged violation will recur" and that the change "completely and irrevocably eradicated the effects of the alleged violation." *Balt. Neighborhoods, Inc. v. LOB, Inc.*, 92 F. Supp. 2d 456, 461 (D. Md. 2000) (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953) and *Cty. of L.A. v. Davis*, 440 U.S. 625, 631 (1979)). In Defendants' view, the mere announcement of an intention to change policy would justify dismissal even though actually enacting changes rarely suffices to do so. This perverse result is not the law.

FDA's other arguments are of no moment. FDA cites the Supreme Court's inherent authority to "control the disposition of the casues on its docket," *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936), without acknowledging the Court's explicit command two sentences later that a part urging a stay "must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else," *id.* FDA claims to distinguish the "few cases" that Plaintiffs cite where courts ruled on the lawfulness of agency actions soon to be obsolete, Def.'s Resp. at 4, but does not even acknowledge—much less distinguish—*Chamber of Commerce v. U.S. Department of Labor*, 885 F.3d 360 (5th Cir. 2018), where the Fifth Circuit vacated a rule even though the agency had not only invited comment on replacing it but had actually stayed its ongoing effect. Moreover, such cases are legion. *See* Richard J. Pierce, Jr., *Administrative Law Treatise* § 15.12 (5th ed. 2010) (collecting cases both applying and rejecting prudential ripeness).

FDA also notes that Plaintiffs have filed comments urging modification of the draft guidance, but provides no reason to believe that any final guidance it issues will adopt Plaintiffs' suggestions. *Cf. Lake Pilots*, 257 F. Supp. 2d at 161-62 (challenge partially unripe where agency had *already* issued temporary final rule providing "the precise interim relief that plaintiff itself requested"). Even if FDA ultimately does so, that would not change the fact that *right now*, FDA is allowing all products to be marketed without the premarket review required by law, depriving Plaintiffs of needed information and leading their patients to become addicted to those products.

Given the ongoing effect of the operative Guidance and FDA's inability to say when, or even if, it will be replaced, prompt review of its legality is warranted. Accordingly, Plaintiffs respectfully urge the Court to reinstate the cross-motions for decision as soon as is judicially practicable.

Respectfully submitted,

/s/ Jeffrey B. Dubner
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